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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,088	07/26/2001	Alessandro Lambiase	36226/125733	6075

7590 05/17/2007

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EXAMINER	
HAGOPIAN, CASEY SHEA	
ART UNIT	**PAPER NUMBER**
1615	

MAIL DATE	DELIVERY MODE
05/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/890,088	LAMBIASE, ALESSANDRO	
	Examiner	Art Unit	
	Casey Hagopian	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-15,17-21 and 23-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-15,17-21 and 23-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Applicant's Amendment/Remarks filed 2/9/2007.

MAINTAINED REJECTIONS

The following rejections are maintained:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13-15, 17-21 and 23-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Lambiase (WO 98/48002). Lambiase discloses methods of treating pathologies affecting the internal tissues of the eye by administering between 10 to 500 μg/ml of nerve growth factor to an individual (abstract and page 12, lines 14). The NGF can be administered either topically or over the ocular surface of an individual and treats corneal and/or conjunctival affects (page 12, line 31 – page 13, line 23). In another embodiment, the NGF may be administered by introduction into the anterior chamber of the eye (page 12, lines 17-20). Like the instant application, the NGF may be in the form of an ophthalmic solution or gel and may be administered via a bandage or medical contact lens (page 12, lines 10-13). The NGF medicament can be of human origin and can be used to treat disorders originating from laser treatment (Claim 9, 15).

It is the examiner's position that, inherently, the composition advanced by Lambiase, when applied to the eye, treats the same eye-related disorders as the instant application. Since the essential elements of the Lambiase composition and method are identical to the instant compositions and methods (that is, topically applying a composition comprising 10 to 500 μg/ml of nerve growth factor to an individual), the composition would inherently treat the same disorders as the compositions set forth in the instant application. As such, it is the examiner's position that the composition advanced by Lambiase anticipates the compositions enumerated in the instant claim set.

Claims 13-15, 18-19, 21, 24-28 and 30-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Finkenaur et al. (EP 0312208 A1). Finkenaur discloses aqueous gel formulations comprising 1 to 500 μg/ml of a polypeptide growth factor, such as nerve growth factor (abstract; page 3, lines 25-48; page 4, line 9). Said nerve growth factor can be used for wound healing in the anterior chamber of the eye (abstract) as well as internal incisions and wounds (page 6, lines 9-11). Said wound healing composition can be delivered topically to an individual via a bandage (page 2, lines 41, 49-50), eye drops, salves, etc. (page 6, lines 4-5).

It is the examiner's position that, inherently, the composition advanced by Finkenaur, when applied to the eye, treats the same eye-related disorders as the instant application. Since the essential elements of the Finkenaur composition and method are identical to the instant compositions and methods (that is, topically applying a composition comprising 1 to 500 μg/ml of nerve growth factor to an individual), the

composition would inherently treat the same disorders as the compositions set forth in the instant application. As such, it is the examiner's position that the composition advanced by Finkenaur anticipates the compositions enumerated in the instant claim set.

Response to Arguments

Applicant's arguments filed 2/9/2007 have been carefully and fully considered but they are not persuasive. Applicant's major contention is that it is asserted that the references do not teach all of the limitations as claimed, namely, topical application, NGF passing through the external tissues of the eye to the internal tissues of the eye, and treating the pathologies affecting the internal tissues of the eye. In response, it is respectfully submitted that both references, Lambiase and Finkenaur both teach topically applying NGF to the ocular surface of the eye (see Rejections above). The references also teach treating internal tissues of the eye such as the anterior chamber of the eye and Finkenaur particularly disclose "internal wounds" (page 6). In regards, to the limitation of NGF passing through the external tissues to the internal tissues, it is the position of the examiner that said limitation is inherent to the teachings of the references. Both references teach the claimed composition and method of topically applying the composition comprising NGF, thus it is reasonable to conclude that once the composition is topically applied to the eye, the NGF will pass through the external tissues of the eye to the internal tissues of the eye. Similarly, in regards to the limitation of treating the pathologies affecting the internal tissues of the eye, both references

teach and suggest treating internal tissues such as the anterior chamber and/or internal incisions and wounds as well as the same sources of injury such as injuries incurred by laser treatment. In many instances in applicant's remarks, it appears that applicant is not considering the prior art in their entirety, for example, in discussing "injection" and "NGF". In light of these remarks, applicant is reminded that a reference is relevant as prior art for all that it contains including non-preferred and alternative embodiments. It is also respectfully submitted that, contrary to Applicant's assertions, all of the claim limitations have been properly examined. Thus, for the above reasons, applicant's arguments are unpersuasive. **The art-based rejections under 35 USC 102 are maintained.**

Pertinent Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Urso (USPN 6,063,757) is cited as patents of interest in its disclosure of NGF for use in ophthalmic wound healing. Unlike the instant application, Urso uses a maximum of 1000 mg/ml (1μg/ml) in the formulation.

Conclusion

All claims have been rejected; no claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Casey Hagopian whose telephone number is 571-272-6097. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carlos Azpuru, can be reached at 571-272-0588. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Casey Hagopian
Examiner
Art Unit 1615

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PRIMARY EXAMINER
GROUP 1500